providing a delivery device configured to carry the implantable body to an intended tissue location and implanting the device in tissue;

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associating the body with the delivery device and implanting the body in tissue at the intended location;

applying a surgical adhesive at the site of the implant to secure the body to the tissue.

REMARKS

This amendment is filed in response to the office action dated September 23, 2002. A petition for a three month extension of time and appropriate fee accompany this amendment. In the action, several objections to the drawings and specification in addition to rejections of the claims based on 35 U.S.C. §112, §102 and §103 were presented. The application has been amended to address the rejections made in the office action and specific remarks regarding each of those changes is presented below.

Drawings

Regarding the objection to the reference numeral 6 referring to both "myocardium" and "tissue", applicants point out that the myocardium is a type of tissue and a single reference numeral should be sufficient to identify that single element (tissue). However, to address the objection, applicants have amended the specification to identify reference numeral 6 as "myocardial tissue". Applicants emphasize that the implants of the present invention can be placed in any type of tissue anywhere in the body but the example of placement in the myocardium is illustrated in the drawings. This amendment altering the specification to refer to myocardial tissue with reference to the drawings should not be considered to limit the scope of the invention to myocardial applications only.

The objection to reference numeral 18 as designating both a proximal and distal coil has been addressed by correcting a typographical error in the specification at page 9, line 11. The specification now identifies reference numeral 18 as a proximal coil only.

Regarding the objection to the designations for reference numeral 40, the

specification has been amended so that reference numeral 40 designates an "implant device" only.

The specification has also been amended to address the objection regarding reference numeral 120. Specifically, amendments have been made at page 11 to identify the broad coil tail as reference numeral 128 and the individual turns of the coil as reference numeral 120.

The specification also has been amended to address the objections to the absence of reference numerals 52, 82, 148 and 149 in the specification though shown in the drawings. Reference numeral 52 has been inserted at page 10, line 11 to define the "bulbous shape" at the proximal end of the implant as shown in FIGS. 5 and 6. Reference numeral 82 has been inserted at page 10, line 29 to identify the "distal end" of the full taper device 80 as shown in FIG. 7. FIG. 13 in the drawings has been amended to delete the reference numeral 148. A corrected drawing sheet 5 is provided. Reference numeral 149 is not presently found in the drawings so no correction has been made to address that objection.

Reference numeral 28, identifying the longitudinal axis of the implant is shown in FIG. 1. The "neck" recited in claims 31-33 as shown in the drawings as reference numeral 127 (FIG. 8) in the specification at page 11, line 14, has been amended to specifically recite an extension neck to clarify its identification in the drawings. Support for the identification of the neck is in the claims is found at page 4, lines 31 through page 5, line 1 and page 11, lines 13-15.

Specification

The objection to the absence of continuation data in the first paragraph has been addressed. Specifically, the specification has been amended to recite the present applications is a §371 national stage filing of PCT US 00/13118, which claims priority to U.S. provisional applications 60/134,331 and 60/134,572.

The objection regarding the abstract is not understood. The PCT application upon which this §371 U.S. application is based contains an abstract as required. If the

abstract has some how become lost from the file, applicant's will provide a copy in response to the next action.

Claim Rejections - 35 U.S.C. §112

Regarding the rejection of claim 38 reciting a clinically effective penetration depth, the claim has been amended to delete the language objected to.

Regarding the rejection of claims 1 and 2, claim 1 has been cancelled and claim 2 has been rewritten in independent form incorporating the elements of claim 1. Claim 2 has additionally been amended to correct the obvious grammatical error comparing the profile of the proximal end to the profile of the proximal end. The claim now correctly recites the intended limitation that the proximal portion has a larger profile than the distal portion.

Claim 9 has been amended to delete the descriptive language of "adequate" and now recites a device having longitudinal flexibility.

Claim 11 has been amended to recite that the surgical adhesive is "applied" to the device. The new language is consistent with the adhesive description presented in the specification.

The rejection of claim 20 for failing to provide antecedent basis for the term "individual coils" is traversed. The claim introduces individual coils properly as a new element, not referring to the element as "the" or "said" coils, which would indicate prior recitation of the element. The rejection of claims 21 and 22 is traversed for the same reasons.

Claims 26-29 have been amended to recite a "broadly wound coil" as defined in the base claim 22 to address the antecedent basis rejection.

A typographical error in claim 30 has been corrected to change the word "core" to "coil" to address the antecedent basis rejection. The specification has been amended to recite that the neck portion coincides with the extension 127 shown in the drawings. Details of this rejection are discussed above in connection with the drawing objections.

In claim 38 a "clinically effective penetration depth" has been deleted from the claim. The step of "providing a sharp tip delivery device" has been amended to recite a "sharp tip implant delivery device" to provide antecedent basis for recitation of the implant delivery device later in the claim.

Claim 42 has been amended to recite the method step of "providing and implanting".

The rejection of claim 49 is traversed. "Sufficient longitudinal flexibility" is defined in the remaining language in the claim as "sufficient to absorb migratory forces applied on the device by surrounding tissue after implantation".

Claim Rejections - 35 U.S.C. §102

Claim 1 has been cancelled and claim 2 has been rewritten in independent form, incorporating the elements of claim 1. Additionally, claim 2 has been amended to correct a typographical error appearing in the claim as filed. The claim now recites that the proximal portion has a larger profile than the distal portion of the implant.

Rejections Based on U.S. Patent 6,007,544 (Kim)

In the office action, claims 1-24 were rejected as being anticipated by U.S. patent 6,007,544 (Kim). Applicants request reconsideration of the rejection in light of the cancellation of claim 1 and amendment of claim 2, from which all claims 3-24 depend. The Kim patent does not disclose an implant device having a proximal portion defining a larger profile than the distal portion of the device.

In Kim Col. 23, line 15 through col. 24, line 32 describes the delivery of the implant. The implant described is preferably a shape memory alloy having an initial configuration with a small profile along its length, as shown in FIG. 38A, to facilitate insertion. The final configuration of the implant after placement in a patient and being exposed to the elevated temperature of the body is shown in FIG. 38C. In the final configuration of the implant, the proximal and distal ends 404 and 402 are flared to larger diameters so as to become restrained in position, one end trapped in an internal lumen of an unobstructed blood vessel and the other becomes retained against the

exterior surface of the vessel to form a cuff that will serve as a bypass graft. The device shown in FIG. 38B is merely a representation of the transformation of the device shown in FIG. 38A when exposed to a temperature increase at one of its ends. Ultimately, after implantation, the device disclosed by Kim will resemble the cuff shown in FIG. 38C in which both ends are flared. Nowhere in Kim is it suggested that the implant remain in the configuration shown in FIG. 38B and, indeed, the implant would not work for its intended purpose to secure a bypass graft if it were to retain a configuration in which only one end was cleared. Accordingly, claim 2 and all of the claims dependent from it should not be considered to be anticipated by Kim.

Rejections Based on U.S. Patent 5,810,836 (Hussein)

Claim 38 has been amended to recite that the flexible implant has a proximal portion defining a broader profile than the distal portion. The Hussein patent does not disclose an implant having that configuration. Hussein discloses several embodiments of his implant device. The spring coil device, defined by Hussein as being flexible, such as shown in FIG. 5, has a tail portion 27; however, the tail does not define a profile that is greater than that of the distal portion of the implant as is defined in applicants' claim 38. The several embodiments of Hussein that are rigid tubular structures appear to terminate in a cap structure such as element 5, shown in FIG. 2; however, the implants are not flexible as is defined in applicants' claims. Accordingly, claims 38 and 40, 42 and 45 which depend from claim 38 should be considered to define patentably over Hussein.

The rejection of claim 49 as anticipated by Hussein is traversed. Claim 49 defines a method of implanting an implant device configured to resist migration in tissue comprising providing a flexible spring body having sufficient longitudinal flexibility to absorb migratory forces applied on the device by surrounding tissue after implantation. Hussein does not address forming his implants to have sufficient longitudinal flexibility to absorb migratory forces applied by the surrounding tissue. To the contrary, Hussein states that an anchoring coil 27 prevents detachment of the stent from the heart wall. (col. 3, lines 36-39). Accordingly, claim 49 should not be considered to be anticipated

by Hussein.

Claim Rejections Based on 35 U.S.C. §103

Claim Rejections Based on U.S. Patent 4,130,904 (Whalen)

Claims 25-29 depend indirectly from claim 2, which has been amended to define a proximal portion defining a profile that is larger than the profile of the distal portion. As discussed above in connection with the §102 rejections based on Kim, the Kim patent does not disclose an implant having a proximal portion with a larger profile than the distal portion. Whalen does not supplant Kim to provide this teaching. Nowhere in the Whalen patent is it disclosed that the implant should have a proximal portion defining a larger profile than the distal portion. Accordingly, because neither Whalen nor Kim provide a teaching of that element of claim 2 (and claims 25-29 dependent on claim 2), the rejection should be withdrawn.

Claim Rejections Based on the combination of U.S. Patent 6,007,544 (Kim) and U.S. Patent 5,824,059 (Wijay)

Claims 30 and 34-37 stand rejected as obvious by Kim in view of Wijay. Claims 30 and 34-37 depend from claim 2 and include the limitation of a proximal portion having a larger profile than the distal portion. As discussed above, the Kim patent does not disclose an implant having that configuration. The Wijay patent also fails to disclose that configuration. Accordingly, where neither Kim nor Wijay disclose or suggest an element of the rejected claims, their combined teaching cannot be said to so disclose that limitation. Accordingly, the rejection based on the combination of Kim and Wijay should be withdrawn.

Claim Rejections Based on the Combined Teaching of the Kim, Whalen and Hussein Patents

Claims 31-33 stand rejected as obvious in view of the combined teachings of Kim, Whalen and Hussein. Claims 31-33 depend from claim 2 and include the limitation of a proximal portion defining a larger profile than the distal portion. Kim, Whalen and Hussein all fail to provide a teaching of that configuration as has been discussed above. Accordingly, the rejection of claims 31-33 based on their combined teachings should be

withdrawn.

Additional Claim Rejections Based Upon Hussein

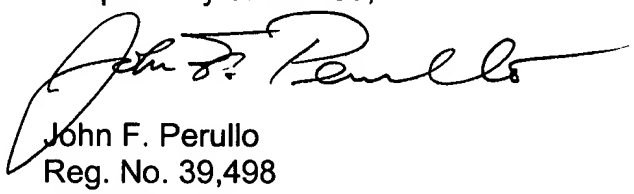
Claims 39, 41 and 43-44 stand rejected as obvious in view of the Hussein patent. Claims 39, 41 and 43-44 depend from claim 38, which has been amended to recite that an implant is provided having a proximal portion profile that is larger than the profile of the distal portion. As discussed above, the Hussein patent does not disclose an implant having that configuration. Accordingly, the rejections of claims 39, 41 and 43-44 should be withdrawn.

Claim Rejections Based on the Combination of Hussein in view of U.S. Patent 5,891,113 (Murphy-Chutorian)

Claims 46-48 stand rejected as obvious by the Hussein patent in view of Murphy-Chutorian. Claim 46 has been amended to recite an implantable body having a proximal portion profile that is larger than the distal portion profile. Neither Hussein nor Murphy-Chutorian disclose or suggest such a configuration. Accordingly, their combined teachings should not be considered to render clam 46, nor claims 47-48 dependent on claim 46 as obvious.

For the foregoing reasons all pending claims should be considered to define patentable subject matter and their allowance in the next action is earnestly solicited.

Respectfully submitted,



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Docket No.: B0410/7277
Date: March 24, 2003

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification

Please insert the following new paragraph before the "Field of the Invention" beginning on line 2 of page 1:

Related Application

This application is a §371 national stage application of PCT/US00/13118, which claims priority to U.S. provisional application serial nos. 60/134,331 filed May 14, 1999 and 60/134,572 filed May 17, 1999.

Paragraph beginning at line 3 of page 9 has been amended as follows:

The implant device is particularly useful in treating ischemic tissue such as that often occurs in a myocardium of the heart. As shown in FIG. 1 the implant device may be inserted into the tissue 6, such as that of the myocardium, ~~6~~ through the epicardial surface 20 at entry site 24 such that the device extends the majority of the thickness of the myocardium towards ~~endocarial~~ endocardial surface 22. Also, the device is fully implanted within the tissue such that the proximal laterally extending arm 16 is submerged within the tissue.

Paragraph beginning at line 9 of page 9 has been amended as follows:

FIG. 2 shows an end view of the device 2 and in particular the laterally extending arm 16, which is configured to prevent migration of the device. As is seen in FIG. 2 the arm extends from the most ~~distal~~ proximal coil 18 in ~~an~~ a tangential direction from the round coil. The arm 16 then curves slightly in the direction of the curvature of the coil. Preferably the lateral extent of the arm beyond the outside diameter of the device is approximately 1 - 3 mm. Generally the diameter of the body 8 of the coil is preferably on the order of 2 - 3 mm. The arm serves to provide increased surface area engaged

with the tissue to prevent migration in an axial direction through the tissue. Furthermore, the implantation of the arm into the tissue causes it to prevent rotation of the device so that the device cannot back out of its tissue implant site.

Paragraph beginning at line 1 of page 10 has been amended as follows:

FIG. 5 shows another preferred embodiment of the implant device. A semi-tapered coil spring implant device 40 may also provide adequate anchoring in dynamic tissue such as the tissue of the myocardium while meeting the objectives of the invention. The implant device 40 comprises a helical coil spring 42 having a proximal portion 44 and a distal portion 46. The individual coils 48 of the spring 42 increase in diameter through the proximal portion 44. Each coil increases in size in the proximal direction. However, the coils of the distal portion 46 are a constant diameter that is somewhat smaller than the diameter of the coils of the proximal portion. The most proximal coil 50 does not extend laterally outward as with the previous embodiment, rather it terminates in its position as part of the helical coil arrangement. The proximal end of the coil may be formed to have a bulbous shape 52 to further resist penetration of the tissue after the device has been implanted. As with the previous embodiment, the tissue tends to herniate at points 26 along the length of the implant. In experiments, the implant device 40 has shown to resist migration and rotation by virtue of the partial increase in taper at the proximal portion 44 of the device. This configuration may also serve to resist migration due to the enhanced flexibility of the proximal coils by virtue of their increased diameter. Increasing the overall diameter of the proximal coils (while ~~maintaing~~ maintaining the same filament thickness) serves to increase the flexibility of those coils.

Paragraph beginning at line 19 of page 10 has been amended as follows:

FIG. 6 shows an end view of the implant device 40 having a partial taper at the proximal portion 44. As with the first embodiment, the most proximal coil 50 is submerged within the tissue 6 when the device is implanted. The submersion of the

most proximal coil provides the advantages detailed above and additionally avoids placing a section of the coil across the transition between the tissue and tissue surface, which may tend to move differently placing an increased stress on the device and possibly leading to premature failure. FIG. 7 shows a variation of the preferred embodiments discussed above wherein the increasing taper is present throughout the length of the device 80 such that each coil increases in diameter in a direction from the distal end ~~80~~ 82 to the proximal end 84. The full taper embodiment 80 is believed to offer the same benefits as described in connection with the device shown in FIG. 5. In the above described tapered embodiments the smaller distal coils 46 may define a ~~diamenter~~ diameter on the order of approximately 2.2 millimeters measured to the outside diameter of the coils and the larger diameter, maximum extent of the taper may be on the order of 4.5 to 5 millimeters. The devices are preferably on the order of 7 - 8 mm in length.

Paragraph beginning at line 3 of page 11 has been amended as follows:

FIG. 8 shows an alternate embodiment of an implant device having an anchoring mechanism. The coil device has an interior 98, which is defined by the individual turns 120 of the coil. The helical coil 96 defines a frame, which holds back surrounding tissue so that blood may pool in the interior chamber, coagulate and become fibrin. Spaces 122 between individual turns of the coil permit communication between the interior chamber 98, where fibrin will grow and the blood and tissue that surround the device. Open ends 124 also permit communication between the interior chamber 98 and surrounding tissue. The coil 96 has a tail 128 configured to resist excessive penetration of the device into the subject tissue so that the overall depth that the device is implanted in the tissue is controlled. The tail ~~28~~ 128 may be configured in a variety of forms. The example of a tail shown in FIG. 8 comprises a single broad coil joined to the main body 125 of the device by an extension neck 127, which may be a continuation of the most proximal coil 116. When the device is implanted in tissue, the broad coil of the tail is positioned to be flush with the surface of the tissue. The broad coil tail distributes the

migratory forces experienced by the device over a broad area of tissue surface. The tail resists penetration of tissue surface thereby preventing migration of the device further into the tissue. Additionally, filament 126 from which the coil is formed may be a solid material or may, itself, be a coil spring structure having a plurality of openings between turns of the coil, which serve to permit herniation of surrounding tissue into the coil for anchoring capability. The broad coil ~~120 defining~~ tail 128 has a proximal end 130 which is preferably joined to the broad coil to maintain the coil circular shape. The proximal end 130 can be joined to the broad coil 128 by a variety of means such as welding as is shown by weld 132.

Paragraph beginning at line 26 of page 11 has been amended as follows:

FIG. 9 shows an alternative embodiment of joining the proximal end 130 to the broad coil tail 128. The alternative embodiment comprises wrapping the portion of the filament adjacent the proximal end 130 around the broad coil tail 128 in several turns 134. FIG. 10 shows another alternative embodiment useful for joining the proximal end 130 of the coil 96 to the broad coil tail 128. The alternative embodiment utilizes a malleable sleeve 136 to encompass both a portion of the broad coil tail 128 and the distal end of the coil 130. The malleable sleeve is then crimped to mechanically grasp the distal end 130 and broad coil and join them so that the circular shape of the broad coil tail 128 is maintained.

Paragraph beginning at line 3 of page 12 has been amended as follows:

The broad coil tail 128 need not be a circular shape but may have a variety of broad shapes capable of serving to disperse migratory forces over a broad surface area of tissue when the device is implanted. FIG. 11 shows a possible non-circular shape for the broad coil comprising a star shaped 137. FIG. 12 shows yet another alternative embodiment for the shape of the broad coil tail 128. In FIG. 12 a somewhat oval broad coil 138 is shown. Additionally, the broad coil 138 has plurality of distally projecting protrusions 139, which may increase the grasp of the coil into the tissue to prevent migration.

Paragraph beginning at line 1 of page 14 has been amended as follows:

An alternative method of anchoring the device comprises applying a surgical adhesive to the site of the implant such that adhesive is joined to the implant device and to surrounding tissue so that it is adhered. As described previously, one method of applying the surgical adhesive may comprise applying it directly at the surgical site or manually or delivering a quantity of surgical adhesive through the obturator delivery device directly to the cavity ~~18~~ 14 created in the tissue by the device.

In the Claims

Claim 1 has been cancelled.

Claim 2 has been amended as follows:

2. (Amended) A tissue implant device ~~as defined in claim 1 further~~ configured to resist migration in tissue comprising a flexible body having proximal and distal portions each defining a profile, the proximal ~~end~~ portion having a larger profile than the ~~proximal end~~ distal portion.

Claim 8 has been cancelled.

Claim 9 has been amended as follows:

9. (Amended) A tissue implant device as defined in claim ~~1~~ 2 wherein the device is configured to resist migration by exhibiting ~~adequate~~ longitudinal flexibility to substantially absorb migratory forces placed on it by the surrounding tissue.

Claim 10 has been cancelled.

Claim 11 has been amended as follows:

11. (Amended) A tissue implant device as defined in claim 1 further comprising a surgical adhesive ~~associated with~~ applied to the device.

Claim 18 has been amended as follows:

18. (Twice Amended) A tissue implant device as defined in claim 7 wherein ~~the flexible body comprises and helical spring and~~ the tail is formed by a more broadly wrapped coil adjacent to the proximal portion of the body forming an arm that extends laterally from the longitudinal axis of the device in the diameter of coils that comprise the body of the spring.

Claim 20 has been amended as follows:

20. (Amended) A device as defined in claim 8 wherein individual coils of the helical spring have a constantly increasing diameter from the ~~proximal~~ distal portion to the ~~distal~~ proximal portion.

Claim 22 has been amended as follows:

22. (Amended) A tissue implant device as defined in claim 6 wherein the ~~flexible body comprises a helical spring and the~~ tail comprises a broadly wound most proximal coil of the spring having a diameter that is greater than the diameter of coils of the body of the device.

Claim 26 has been amended as follows:

26. (Amended) A tissue implant device as defined in claim 25 wherein the proximal end is joined to the ~~broad loop~~ broadly wound coil by being wrapped around the loop.

Claim 27 has been amended as follows:

27. (Amended) A tissue implant device as defined in claim 26 wherein the proximal end of the ~~coil~~ spring extends distally from the ~~broad loop~~ broadly wound coil after it has been wrapped about the ~~broad loop~~ broadly wound coil to serve as a barb.

Claim 28 has been amended as follows:

28. (Amended) A tissue implant device as defined in claim 25 wherein the proximal end is joined to the ~~broad loop~~ broadly wound coil by welding.

Claim 29 has been amended as follows:

29. (Amended) A tissue implant device as defined in claim 25 wherein the proximal end of the ~~coil~~ spring is joined to the ~~broad loop~~ broadly wound coil by a malleable sleeve crimped around the proximal end and broadly wound coil to secure the proximal end to the coil.

Claim 30 has been amended as follows:

30. (Amended) A tissue implant device as defined in claim 22 wherein the broadly wound ~~core~~ coil is non-circular.

Claim 38 has been amended as follows:

38. (Amended) A method of implanting a tissue implant device comprising:

providing an implant device having a flexible body with proximal and distal ends and an anchoring tail at the proximal end that defines a larger profile than the distal end of the implant;

providing a sharp tip implant delivery device configured to penetrate tissue and releasably retain the tissue implant device;

associating the implant device with the implant delivery device;

accessing the desired tissue implant site;

applying a penetrating force to the implant and implant delivery device combination such that the combination penetrates tissue ~~to a clinically effective penetration depth~~ to implant the device;

withdrawing the implant delivery device from the implanted implant device.

Claim 42 has been amended as follows:

42. (Amended) A method of implanting a tissue implant device to promote angiogenesis within a tissue comprising:

providing and implanting a tissue implant device configured to be anchored within tissue so that it does not migrate from the tissue after implantation comprising a flexible body having proximal and distal portions each defining a profile, the proximal portion having a larger profile than the distal portion.

Claim 46 has been amended as follows:

46. (Amended) A method of anchoring a tissue implant device within tissue comprising:

providing an implantable body having a proximal portion and a distal portion each defining a profile and wherein the profile of the proximal portion is larger than that of the distal portion;

providing a delivery device configured to carry the implantable body to an intended tissue location and implanting the device in tissue;

associating the body with the delivery device and implanting the body in tissue at the intended location;

applying a surgical adhesive at the site of the implant to secure the body to the tissue.